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EXAMINER

YU, GINA C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1617

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,721

Applicant(s)

HIRAKI ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of amendment filed on October 29, 2002. Claims 1-13 are pending. Claim rejections under 35 U.S.C. § 103 as indicated in the previous Office action dated June 18, 2002 are withdrawn in view of further consideration.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The description of the weight amount of the components as recited in claim 4 is vague and confusing. Applicants' amendment in response to the previous Office action still does not remove the confusion. The problem here is the recitation in lines 2-4, which essentially reads - component A is 2 to 100 parts by weight for component B per part by weight of component A. Appropriate correction is required.

In claim 5, the use of the term "composition" to further limit the "preparation" in claim 1 renders the claim vague and indefinite. The term "preparation" as recited in claim 1 and the depending claims thereof has been interpreted to mean "composition".

If a preparation can be further limited to a composition as recited in claim 4, it is not clear what applicants mean by the term "preparation".

Claim 6 is rejected for depending on an indefinite base claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-6, 8, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maybeck et al. (US 5034228) ("Maybeck") in view of Abstract of JP 4338311 A, assigned to Yakult Honsha (WPI Acc No 1993-012129/199302) ("Yakult Abstract").

Maybeck teaches a topical composition useful for cosmetics use, comprising lamellar phases containing retinoid. See abstract. The reference teaches that the "amount of the retinoid . . . in the lipidic phase constituting the double layer of the lamellar phase or liposomes is not critical and may reach 40 % by weight", and that preferably 0.01-5 % by weight of the retinoid is used. See col. 3, lines 18 – 23. See instant claims 8 and 9. Maybeck also teaches that using cholesterol is also well known in the art. See col. 2, lines 53-57; Example 4; instant claim 11. The reference further teaches that a lotion formulation comprising the lamellar structure is well known in the art. See Example 13; instant claim 6. The reference fails to teach fatty acid monoglyceride.

Yakult Abstract teaches a cosmetic composition containing lamellar material based on fatty acid monoglyceride(s), which provide good moisture retention and good feel on skin. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition in the Maybeck by substituting the lamellar material with the material based on fatty acid monoglyceride(s), as suggested by Yakult Abstract, because of the expectation of successfully producing a cosmetic composition with good moisture retention and good feel on skin.

2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maybeck and Yakult abstract as applied to claims 1-6, 8, 9, and 11 above, and further in view of Yiournas et al. (US 5013497).

Maybeck and Yakult abstract fail to teach that the lamellar phase is in multilamellar structure.

Yiournas generally teaches that multilamellar structure is "considered best for encapsulation or transportation of lipophilic materials" due to the relatively large quantities of lipid in the lipid bilayers therein. See col. 1, lines 21 – 57.

Given the general teaching of retinoid composition with lamellar structure in the combined references, it would have been to one of ordinary skill in the art at the time the invention was made to have looked to the prior arts such as Yiournas for the specific types of liposome structures and/or formulations because of the expectation of successfully producing a composition with encapsulation or transportation of large quantity of lipophilic materials such as retinoids.

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3. Claims 1-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur (US 5260065).

Mathur teaches paucilamellar lipid vesicles made of a blend of amphiphilic lipids. The reference teaches that glyceryl monostearate is among the most preferred lipids used. See col. 3, lines 41 – 51. See instant claims 12 and 13. While the reference teaches that the lipids therein are not capable of forming lamellar by itself, secondary lipids and/or cholesterol is used to form lamellar phase. See col. 3, line 65 – col. 4, line 11. Examiner notes that the scope of the instant claims is open to include lipids or cholesterol other than fatty acid monoglycerides.

Examples 2 and 5 illustrate retinoic acid formulations wherein the retinoic acid is encapsulated within the vesicles. Example 5 employs glyceryl distearate and cholesterol. While Mathur does not show specific formulation comprising glyceryl monostearate, the reference teaches that glyceryl monostearate is nevertheless a preferred lipid in the invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the exemplified formulations in Mathur by substituting the glyceryl distearate with glyceryl monostearate as motivated by the reference, because of the expectation of successfully producing a lamellar vesicle composition with similar properties.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur claims 1-8 and 10-13 above, and further in view of Yiournas et al. (US 5013497).

While Mathur is directed to paucilamellar vesicles, the reference does not teach multilamellar structures.

Yiournas generally teaches the advantages of both types of vesicles. According to the reference, while paucilamellar vesicles can transport large quantities of aqueous or lipophilic materials, their large size can preclude approach to certain tissues. See col. 1, lines 42 –68. Multilamellar vesicles are on the other hand said to be “best for encapsulation or transportation of lipophilic materials” because of the relatively large amount of lipid in the lipid bilayers therein. See col. 1, lines 53 – 60. No disadvantage associated with the size of the multilamellar vesicle structure is mentioned.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the paucilamellar vesicle formulations in Mathur by formulating multilamellar vesicles as motivated by Yiournas because of the expectation of successfully producing lipid vesicles that can similarly encapsulate and transport large quantities of lipophilic materials.

Response to Arguments

Applicant's arguments filed on October 29, 2002 have been considered but are not persuasive.

Applicants argue that the present invention produces superior results compared to the Maybeck formulation. The declaration filed on October 29, 2002 has been fully considered. The declaration and the disclosure in the specification indicate that using fatty acid monoglycerides in lamellar formulation, in comparison with soybean lecithin,

unexpectedly produces better formation of lamellar structure and superior odor-suppressing property.

It is noted that in order to overcome a prima facie obviousness applicants must show greater than expected results by clear and convincing evidence which commensurate with the scope of the claims. See MPEP § 716.02. In this case, examiner views that no “greater than expected” results are shown in producing lamellar phase from fatty acid monoglycerides.

Examiner reiterates that a routineer would have been motivated to combine the Maybeck and Yakult references to formulate a vitamin A composition with by forming lamellar structures from fatty acid monoglycerides. The motivation is to use the fatty acid monoglycerides is found in the Yakult abstract. It is viewed that the issue here is not whether using fatty acid monoglycerides for lamellar formulation or the results obtained thereby is surprising, for such practice is well known and would have been obvious to a routineer: rather, the issue is whether the alleged superior properties of the lamellar formulations by fatty acid monoglyceride are greater than expected at all.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
February 10, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER 2/10/03